Complete Summary

GUIDELINE TITLE

Rotator cuff tear.

BIBLIOGRAPHIC SOURCE(S)

Rotator cuff tear. Philadelphia (PA): Intracorp; 2004. Various p.

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from July 1, 2004 to July 1, 2006.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide

to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Rotator cuff tear

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Orthopedic Surgery
Physical Medicine and Rehabilitation
Sports Medicine

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of rotator cuff tears that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with a rotator cuff tear

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests
    - X-rays
    - Magnetic resonance imaging (MRI)
    - Arthrogram
    - Arthroscopy

Treatment/Management

1. Rest
2. Work restriction
3. Avoidance of painful activities
4. Nonsteroidal anti-inflammatory drug (NSAID)
5. Steroid injection
6. Exercise
7. Surgery
    - Acromioplasty
    - Excision of damaged tendon and suturing to a bony trough
    - Arthroscopic repair
8. Referral to specialists
9. Physical therapy
10. Chiropractic treatment

MAJOR OUTCOMES CONSIDERED

- Pain relief
- Ability to function

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as -the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Shoulder pain
- Stiffness
- Weakness
- Difficulty performing activities of daily life/living (ADLs) (driving, donning clothing)
- Inability to sleep on affected side

Objective Findings

- Stage I
  - Point tenderness at greater tuberosity and acromion
  - Painful arc of motion with abduction
  - Shoulder pain worse with resistance
  - Tender long head of the biceps
- Stage II
  - Same findings, but more severe
  - Partial thickness tears are often more painful than full thickness, because of tension on attached tendon fibers.
  - Shoulder stiffness
  - (+) Codman's sign (arm is passively abducted; when support is removed and the deltoid muscle contracts, pain is elicited)

        - (+) Supraspinatus test (strength in resisted abduction is measured with arm at 90 degrees shoulder abduction; shoulder is then internally rotated and flexed forward to 30 degrees; if resisted abduction in this position is weakened or painful, tear or inflammation is indicated)
- Stage III
    - Passive range of motion greater than active
    - Muscle wasting
    - Painful arc of motion
    - Pronounced weakness on external rotation
    - Point tenderness as above
    - Normal to limited range of motion
    - (+) drop test – inability to lower arm slowly or smoothly from 90 degrees shoulder abduction OR inability to keep passively abducted arm straight out
    - Subacromial crepitus on abduction and rotation
    - Supraspinatus and infraspinatus muscle atrophy

Diagnostic Tests

- X-rays
- Magnetic resonance imaging (MRI)
- Arthrogram – may be useful in early detection of complete full-thickness tears; also for those who cannot have MRI due to implantable devices
- Arthroscopy

Differential Diagnosis

- Cervical spine pathology, with upper extremity radiculopathy (see Intracorp guideline Neck Pain, with Radiculopathy/Myelopathy)
- Impingement syndrome
- Bicipital tendinitis (see Intracorp guideline Bicipital Tendinitis)
- Fracture (see Intracorp guideline Humeral Fracture)
- Dislocation or subluxation (see Intracorp guideline Acromioclavicular and Glenohumeral Dislocation)
- Nerve injury, such as axillary nerve damage
- Suprascapular neuropathy
- Bursitis
- Adhesive capsulitis (see Intracorp guideline Adhesive Capsulitis)
- Brachial plexus injury (see Intracorp guideline Thoracic Outlet Syndrome)

<u>Treatment Options</u>

- Rest shoulder
- Work restriction (no overhead or above the shoulder work, reaching; possibly no work with affected arm, no heavy lifting, pushing, pulling, etc.)
- Avoidance of all painful activities
- Nonsteroidal anti-inflammatory drug (NSAID)
- Steroid injection (1 to 2, with 4 weeks in between if second one administered)
- Exercise regimen after pain is successfully controlled (prevents adhesive capsulitis which is a common complication because of patient "splinting of arm" due to pain)

- Surgery – debridement and surgical repair of partial thickness tears should depend on the extent of tear and the age/activity level of the individual.
    - If defect involves <50% of the cuff thickness, acromioplasty and debridement generally sufficient
    - If defect thicker or long, excision of damaged tendon and suturing to a bony trough is indicated.
    - Arthroscopic repair appropriate for small to medium full thickness tears as well (up to 10 cm) (superior labrum anterior to posterior [SLAP] repair)
        - Pendulum exercises begun the day following surgery
        - Passive range of motion (ROM) end of week 1 following surgery
        - At 3 weeks, active exercises for a period of 4 to 6 weeks physical therapy (PT)
- (Note: State jurisdictional guidelines may supersede the recommendations of this guideline.)

Duration of Medical Treatment

- Optimal: 45 day(s); maximal: 120 day(s)

Additional provider information regarding primary care visit schedules, referral options, frequency and duration of specialty care, physical therapy, chiropractic treatment, and durable medical equipment are provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals for the following scenarios:

- Resolving stage I tear
- Resolving stage II tear
- Resolving III tear
- After surgical intervention

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of rotator cuff tears that assist medical management leaders in making appropriate benefit coverage determinations

POTENTIAL HARMS

None stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Rotator cuff tear. Philadelphia (PA): Intracorp; 2004. Various p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2004)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)

Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

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Reprints of complete guideline content may be purchased for $35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on December 3, 2004. The information was verified by the guideline developer on January 4, 2005. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the

U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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